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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,057	07/23/2003	Edward N. Hill	8789-16CT2	3292

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EXAMINER
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BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/628,057	<b>Applicant(s)</b> HILL ET AL.	
	<b>Examiner</b> Barbara P. Badio, Ph.D.	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,10,13-18,21,24-29 and 32-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,10,13-18,21,24-29 and 32-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

**Final Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Double Patenting***

2. The rejection under the judicially created doctrine of obviousness-type double patenting over claims US Patent No. 6,844,334 is made moot by the filing of a terminal disclaimer.
3. The rejection under the judicially created doctrine of obviousness-type double patenting over claims US Patent No. 6,660,726 is made moot by the filing of a terminal disclaimer.
4. The rejection under the judicially created doctrine of obviousness-type double patenting over claims US Patent No. 6,855,703 is made moot by the filing of a terminal disclaimer.
5. The objection to claims 35 and 36 under 37 CFR 1.75 as being a substantial duplicate of claims 33, and 34, respectively is maintained.

Applicant argues the claims may be differentiated at position C(17) that is either a hydroxyl or oxygen. Applicant's argument was considered but not persuasive for the following reason.

Claim 35 recites the identical compound recited by claim 33, i.e., the claimed compound having a hydroxyl group at C(17). The same is true for claims 34 and 36, i.e., they both recite the claimed compound having a 17-oxo group. Therefore, claim 35 is a duplicate of claim 33 whereas claim 36 is a duplicate of claim 34.

For this reason and those given in the previous Office Action, the objection to claims 35 and 36 under 37 CFR 1.75 as being a substantial duplicate of claims 33, and 34, respectively is maintained.

***Claim Rejections - 35 USC § 112***

**6. The rejection of claims 18 and 29 under 35 USC 112, first paragraph is withdrawn.**

**7. The rejection of claims 33-36 under 35 USC 112, first paragraph is maintained.**

Applicant argues that "page 3, lines 1-4 illustrate these compounds and glucuronides" and that figures in the application illustrate the specific peaks. Applicant's argument was considered but not persuasive for the following reason.

The disclosure of glucuronides or the specific peaks in the specification does not provide support for the specific compounds as recited by the instant claims because

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there is no correlation between said disclosure(s) and said compounds. In fact, there is no reference to the instantly claimed compounds in the present specification.

It is also noted that parent case US Application No. 09/800,614 identifies identical peaks for compounds having different substituents in the 3-position (see claims 1-4) and, thus, said peaks are not specific for the claimed compounds or the group attached to the 3-position of the instantly claimed compounds.

For these reasons and those given in previous Office Action, the rejection of claims 33-36 under 35 USC 112, first paragraph is maintained.

**8. The rejection of claims 5, 14 and 25 under 35 USC 112, second paragraph is withdrawn.**

9. The rejection of claims 1, 4, 6, 7, 10, 13, 15-18, 21, 24, 26-29 and 32 under 35 USC 112, second paragraph is maintained.

Applicant argues "it is at **this** position where a ketone is formed, not at the carbon that the R<sub>4</sub>-R<sub>7</sub> or R<sub>10</sub>-R<sub>13</sub> is attached". Applicant's argument was considered but not persuasive for the following reason.

Applicant's argument that ketone is not formed at the carbon that R<sub>4</sub>-R<sub>7</sub> or R<sub>10</sub>-R<sub>13</sub> is attached is unclear since the definition of the groups attached at said carbon(s) atom includes a ketone. If the ketone is not formed at these carbons where is it formed?

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For this reason and those given in previous Office Action, the rejection of claims 1, 4, 6, 7, 10, 13, 15-18, 21, 24, 26-29 and 32 under 35 USC 112, second paragraph is maintained.

### ***Other Matters***

10. The removal of the term "Novel" from the title of the invention is requested.

### ***Claim Rejections - 35 USC § 102***

11. The rejection of claims 1, 4-7, 10, 13-16, 21 and 24-27 under 35 USC 102(b) over Harnik (IL 25265) is maintained.

Applicant argues the reference does not teach or suggest the claimed compounds having the recited substituents at the 3-position or that the compounds are present in chemically pure form. Applicant's argument was considered but not persuasive for the following reasons.

The claimed compounds include conjugates thereof and, thus, the skilled artisan in the art would consider the compounds taught by Harnik to be conjugates of the claimed compounds. The examiner notes the definition of "conjugates" set forth in the present specification (see page 8, lines 10-12) and the level of skill of the ordinary artisan in the art at the time of the present invention.

Applicant also argues that the prior art does not teach the pure form of the compounds. However, the reference teaches the estrogenic properties of the compounds and, thus, the ordinary artisan in the art would expect that the compound(s)

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would be in pure form. It is known in the pharmaceutical art to obtain compounds in pure form in order to test for beneficial properties. The fact that the reference is silent as to the purity of the compound does not imply that it is not. Applicant has not provided evidence that the prior art compound is not in pure form.

For these reasons and those given in previous Office Action, the rejection of claims 1, 4-7, 10, 13-16, 21 and 24-27 under 35 USC 102(b) over Harnik (IL 25265) is maintained.

***Claim Rejections - 35 USC § 103***

12. The rejection of claims 17, 18, 28, 29 and 32 under 35 USC 103(a) over Harnik (IL 25265) is maintained.

Applicant's argument and the examiner's response are as discussed above in #10.

In addition, applicant argues there is no motivation taught or suggested by the reference that its set of compounds would be useful for estrogen therapy. The examiner notes that it is well known in the art to utilize estrogenic compounds for estrogen replacement therapy. Thus, the use of prior art estrogenic compounds for estrogen replacement therapy would be obvious to the skilled artisan in the art.

For these reasons and those given in previous Office Action, the rejection of claims 17, 18, 28, 29 and 32 under 35 USC 103(a) over Harnik (IL 25265) is maintained.

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### ***Conclusion***

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Telephone Inquiry***

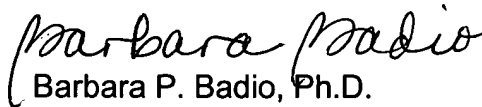
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB

August 15, 2005